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January 22, 2015

VIA ELECTRONIC MAIL

The Honorable Mitchell S. Goldberg
7614 James A. Byrne U.S. Courthouse
United States District Court for the
Eastern District of Pennsylvania
601 Market Street
Philadelphia, Pennsylvania 19106-1797

Re: ***King Drug Company of Florence, Inc. v. Cephalon, Inc., et al.***
Civ. A. No. 2:06-cv-1797 (E.D. Pa.)

Dear Judge Goldberg:

I write on behalf of the Direct Purchaser Class Plaintiffs ("DPCPs") in response to the Court's Order dated January 6, 2015. While we have advocated for a separate trial on all issues, the DPCPs recognize that there are certain core liability issues – such as the legality of Defendants' conduct, whether Cephalon possessed monopoly/market power, whether the challenged conduct delayed generic competition, and when generic entry would have occurred but for Defendants' conduct – that are common to all parties and may make a single consolidated trial (before the Court and a single jury) more efficient than separate trials on the same issues. With respect to the issue of remedies, however, Supreme Court precedent requires that the quantification of DPCPs' overcharges be determined in a separate trial (although such a trial would be of very limited scope and duration and should not prove burdensome).[1]

Trial(s) on Remedies. The DPCPs are entitled, as a matter of law and fundamental fairness, to have a separate jury consider their overcharge damage claims (once liability is established) without also hearing evidence relating to the relief the other plaintiffs may be seeking. In a direct purchaser overcharge action, it is legally irrelevant that direct purchasers may have "passed on" to downstream purchasers some or all of the overcharges they paid. *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968). The End-Payors's damage claims appear to be based on the theory that they absorbed some of these "passed on" overcharges. The FTC's damages claim

[1] Fed. R. Civ. P. 42(b) provides the Court with substantial discretion to order a separate trial on one or more separate issues.

encompasses overcharges and market harms at a variety of levels.[2] Because the other plaintiff groups are pursuing different types of relief that would necessarily involve some downstream effects – *e.g.*, pass-on damages, lost profits or disgorgement – binding precedent prohibits a single jury from considering the DPCPs' damage claims along with the remedies sought by the other plaintiffs. Consequently should the Court decide to proceed with a "single trial" with respect to liability, the DPCPs are entitled to a separate trial with respect to remedies, including quantification of their overcharge claims. Only by bifurcating trial of liability and damages can the rights of the DPCPs be protected.[3]

Only direct purchasers have standing to recover overcharge damages under federal antitrust law. *Hanover Shoe*; *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). The indirect or pass-on damages the End-Payors seek are available only under state, not federal, law. Recognizing the inherent tension between these two types of damages, the Supreme Court has instructed unequivocally that an "*antitrust defendant is not permitted to introduce evidence that indirect purchasers were in fact injured by the illegal overcharge.*" *Illinois Brick*, 431 U.S. at 724-25 (emphasis added).[4] Consequently, permitting the same jury to consider both direct purchaser and indirect purchaser damage claims would contravene the Supreme Court's holding and cause substantive prejudice to the DPCPs. Similarly, allowing the same jury to hear the DPCPs' overcharge claims together with Apotex's claims for lost profit and the FTC's claims for disgorgement would necessarily invite jury confusion and result in substantive prejudice to the DPCPs.[5]

Bifurcating the trial into separate liability and damage phases has been widely used in antitrust cases including class actions. *See, e.g., Hydrite Chem Co. v. Calumet Lubricants, Co.*, 47 F.3d 887, 890-91 (7th Cir. 1995) (Posner, J.) ("[A]s is commonly done, between liability and damages, the fact of injury belongs in the first trial and the quantification of the injury by means of an assessment of damages in the second."); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 523 (S.D.N.Y. 1996) ("Bifurcation has been widely used . . . in antitrust class actions" to promote judicial economy.);[6] FED .R. CIV. P. 42(b). Further, courts have recognized the requirement of excluding pass-on evidence in a direct purchaser action. *Gulfstream III Assoc., Inc.*

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[2] To be sure, the FTC has already acknowledged that any damages recovered by the direct purchasers would need to be "offset against some award that the FTC would be looking for." *See* 1/23/2014 Hearing Trans. at 51.

[3] This is an issue that was previously raised informally with the Court during the April 8, 2014 conference.

[4] The Court stated further that the longstanding policy of encouraging private enforcement of the antitrust laws "is better served by holding the direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it." *Id.* at 746.

[5] A separate trial limited to determining the direct purchasers' damages (after a prior jury's finding of liability), would not involve a lengthy trial since the jury would only consider the party's evidence (mostly expert) concerning the amount of the overcharge claimed due to delayed generic entry.

[6] *See also, Union Carbide Corp. v. Montell N.V.*, 28 F. Supp. 2d 833, 837 (S.D.N.Y. 1988); *In re Relafen Antitrust Litig.*, No. 01-cv-12239 (D. Mass.) (electronic orders dated December 9 and 10, 2003); *In re Playmobile Antitrust Litig.*, 35 F. Supp. 2d 231, 248 (E.D.N.Y. 1998); *In re Brand Name Prescription Drugs Antitrust Litig.*, No. 94 C 897, 1998 U.S. Dist. LEXIS 9040, at *19-22 (N.D. Ill. June 11, 1998); *In re Ampicillin Antitrust Litig.*, 88 F.R.D. 174, 178-79 (D.D.C. 1980).

v. Gulfstream Aerospace Corp., 995 F.2d 425, 432 (3d Cir. 1993).[7] And very recently in the *Nexium* litigation, Judge Young directed that the trial would be bifurcated between liability and damages and, should liability be established, the direct purchasers' overcharge claim would be tried to a separate jury that would not hear any evidence relating to pass-on. *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass.) (WGY), Dec. 11, 2013 hearing transcript at 11 ("I agree that we're not going to be able to try damages, if damages there are, if any, for the end payors and the direct purchasers in the same proceeding, I can't see how that would be fair."). *See also, In re Nexium Esomeprazole Antitrust Litig.*, No. 12-md-2409, 2013 U.S. Dist. LEXIS 162276, at *42, 50 (D. Mass. Nov. 14, 2013) ("[T]he possibility of multiple proceedings after a classwide liability determination hardly offends the rights of any of these litigants.").

In this letter, the DPCPs only "outline" this issue as it impacts trial structuring, in light of what we believe to be the Court's directive. The substantive issue raised, however, is of critical importance to the DPCPs' effort to enforce their rights under federal antitrust law as well as to further the longstanding policy to encourage vigorous private enforcement of the antitrust laws by direct purchasers. *See, e.g., Perma Life Mufflers, Inc. v. International Parts Corp.*, 392 U.S. 134, 139 (1968). We will of course submit additional briefing, now or at a later date, should the Court require it.

Trial on Liability. With respect to a "single" liability trial involving all parties (with the FTC case to be tried to the Court and the private plaintiffs' cases to a jury), the DPCPs wish to outline the antitrust theories they currently intend to try in order to help the Court consider whether a single trial is feasible and/or manageable:

First, the DPCPs intend to prove that Cephalon committed *Walker Process* fraud in violation of Section 2 of the Sherman Act. *Walker Process Equipment v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). Under *Walker Process*, "enforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act provided the other elements necessary to a §2 case are present." *Id.* at 174.[8] *Walker Process* fraud requires a material omission or false statement to the PTO and the intent to deceive the PTO. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 692 (2d Cir. 2009). And, as in a usual Section 2 case, plaintiffs must prove monopoly power. *See, e.g., Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 n. 3 (3d Cir. 2007).

As to whether Cephalon made a materially false statement or omission, this Court has already determined that its findings of inequitable conduct and invalidity in the *Apotex* patent litigation collaterally estop Cephalon from relitigating in the antitrust trial either the RE'516 patent's validity, or the materiality element of *Walker Process* fraud. Dkt No. 600. Thus, with respect to the DPCPs' *Walker Process* contentions against Cephalon, the only conduct-related element left to try to the jury is whether Cephalon acted with the requisite intent to deceive the

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[7] *See also In re Static Random Access Memory (SRAM) Antitrust Litig.*, MDL No. 07-018189 (N.D. Ca.), D.E. 1222 (Dec. 14, 2010) at 7.

[8] A finding of *Walker Process* fraud does more than strip a defendant of a patent defense under the antitrust laws. It establishes the conduct element of a Section 2 violation and provides the basis for liability and treble damages if the other elements of a Section 2 claim are also established.

PTO, *i.e.*, whether "it did not believe that the information it withheld from the PTO was material at the time it obtained the patent." Dkt No. 600 at 27.[9] And this Court has already held that upon such a showing, Cephalon may not raise a defense that Cephalon lacked knowledge of the fraud at the time the patent was enforced. *FTC Docket,* 08-2141, Dkt. No. 322, at 12-13. The DPCPs note further that Cephalon, having elected not to assert a reliance on counsel defense and having blocked all discovery relating to its subjective beliefs about the strengths and validity of the RE'516 patent, may have an especially difficult task arguing to a jury that despite the prior ruling on invalidity and materiality, it nonetheless did not believe its omissions and misstatements were material.

The other elements of the *Walker Process* case – monopoly power, antitrust impact, and damages – overlap with the proof to be offered as to the reverse payments. The DPCPs will prove that Cephalon possessed market power with respect to modafinil,[10] that but for the fraudulently obtained RE'516 patent generic competition would have occurred earlier, and that as a result Cephalon's conduct has injured the DPCPs. Quantification of those injuries would be tried to a separate jury at a later date (as discussed above). With respect to when generic competition would have occurred absent the fraud, the DPCPs will show, as this Court has noted, that "Cephalon would never have been in the position to institute infringement litigation in first place." *FTC Docket*, 08-2141, *FTC Docket,* 08-2141, Dkt. No. 322 at 11. Therefore, generic entry could have occurred as early as June 2006, when the last of Cephalon's non-patent regulatory exclusivities would have expired.

Second, the DPCPs assert claims that Cephalon and each of the Generic Defendants violated Section 1 of the Sherman Act when they settled patent litigation involving a patent procured by fraud by agreeing to delay generic competition (four separate claims). Even those courts that applied the so-called (and now defunct) "scope of the patent test" recognized that a reverse payment agreement is unjustified if the underlying patent was obtained by fraud or the litigation was a sham. *Actavis*, 133 S. Ct. at 2230.[11] In this regard, the DPCPs' evidence will establish (1) that Cephalon knew of the fraud on the patent office, (2) that the generics discovered the fraud during the patent litigation, and (3) that the generics joined Cephalon in exploiting Cephalon's market power by entering into illicit agreements in which each generic was compensated with some of Cephalon's monopoly profits in exchange for delaying the entry of generic modafinil and dropping their challenges to the fraudulently obtained patent. The same evidence used to establish that the patent was invalid and unenforceable in the *Apotex* patent litigation will be used against the Generic Defendants to prove that the generics violated Section 1 by agreeing to delay competition.

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[9] The Court has noted separately that absent Cephalon's Seventh Amendment right to a jury trial on the issue of intent, the Court's findings in the Apotex litigation would "supply the necessary determinations to establish fraud on the PTO by clear and convincing evidence." *FTC Docket,* 08-2141, Dkt No. 322 at 9 n. 4.

[10] A reverse payment is a "strong indicator of [monopoly] power." *FTC v. Actavis*, 133 S. Ct. 2223, 2236 (2013).

[11] In fact, in the *Actavis* case, the district court held that plaintiffs' claims that the generic defendants "conspired to restrain trade by entering into a settlement of the sham litigation in exchange for a portion of Solvay's monopoly profits," stated an antitrust claim and denied defendants' motion to dismiss on those grounds. *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010), *clarified by, In re Androgel Antitrust Litig.*, 2010 U.S. Dist. LEXIS 113593 (N.D. Ga. Sept. 16, 2010).

While the Court's prior findings will not have preclusive effect with respect to the Generic Defendants, the generics will still have to explain to the jury why the contentions they made in the patent litigation – *e.g.*, "Cephalon did not invent anything . . . [it] simply filed a patent application on the modafinil it purchased from the French company"[12] – did not reflect their true views of the patent's validity and enforceability. And as is the case with Cephalon, the Generic Defendants neither waived the attorney-client privilege in this case nor asserted a reliance on counsel defense. Therefore, they too will be hard-pressed to explain away their pleadings and declarations before the patent court, submitted pursuant to FED. R. CIV. P. 11. Nor can there be any basis for the Generic Defendants to claim unfair prejudice from trying their cases with Cephalon when the very positions they asserted against Cephalon in the patent litigation were ultimately confirmed by this Court. The DPCPs will also have to prove market power, antitrust injury and causation as described above.

Third, the DPCPs intend to prove that each of the settlements between Cephalon and a Generic Defendant constituted an unlawful reverse payment agreement under *Actavis* (four separate claims). As discussed above, Cephalon will be precluded from arguing that the RE'516 patent was valid or that the omissions in its patent application were not "material" to the extent these issues may be relevant. To prove their claims under *Actavis*, the DPCPs must proceed under the "Rule of Reason"; that is, they must show that the anticompetitive effects of the payments outweighed any relevant procompetitive benefit proven by defendants. *United States v. Brown Univ.*, 5 F.3d 658, 668-69 (3d Cir. 1993). DPCPs must also prove market power, injury, and damages, as discussed, although damages commence in December 2006, rather than June 2006.[13]

We hope our comments are helpful and we look forward to discussing trial scheduling and structure at the January 29, 2015 conference.

Respectfully submitted,

Bruce E. Gerstein
Lead Counsel
King Drug Direct Purchaser Class Plaintiffs

cc: all parties (via electronic mail)

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[12] Memorandum of Points and Authorities in Support of Defendant Ranbaxy's Motion for Summary Judgment of Patent Invalidity under the On Sale Bar in *Cephalon, Inc., v. Mylan Pharms., Inc., et al,* Civil Action No. 03-1394 (D.N.J.).

[13] The DPCPs may elect to pursue other liability theories such as violations based on sham litigation as well. *Professional Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49 (1993).

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January 22, 2015

VIA ELECTRONIC MAIL

The Honorable Mitchell S. Goldberg
7614 James A. Byrne U.S. Courthouse
United States District Court for the
Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106-1797

Re: *King Drug Company of Florence, Inc. vs. Cephalon, Inc. et al.*
Civil Action No. 2:06-cv-1797 (E.D. Pa.)

Dear Judge Goldberg:

This letter is submitted on behalf of Plaintiffs in the *Walgreen*, *CVS/Rite Aid* and *Giant Eagle* cases ("Individual Plaintiffs") in response to Your Honor's January 6, 2015 order.

The Individual Plaintiffs agree with Your Honor's suggestions that (1) it would be possible to structure a trial in which all parties participate; and (2) it would be feasible to schedule such a trial to take place this summer.

However, we also agree with the Direct Purchaser Class Plaintiffs that if all of the plaintiffs participated in a single trial it would be necessary to bifurcate liability and damages to avoid irreconcilable jury instructions with respect to the damages claimed by direct purchaser plaintiffs (class and individual) and the End Payors. As the Supreme Court held, in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), it is not a defense to damages in a federal antitrust case that a direct purchaser passed on overcharges to indirect purchasers. As the Direct Purchaser Class Plaintiffs noted in Mr. Opper's letter, the Supreme Court has held that "a direct purchaser suing for treble damages under § 4 of the Clayton Act is injured within the meaning of § 4 by the full amount of the overcharge paid by it and . . . *the antitrust defendant is not permitted to introduce evidence that indirect purchasers were in fact injured by the illegal overcharge*." *Id.* at 724-25 (emphasis added). However, the End Payor Plaintiffs' state law damage claims depend upon proving the very pass-on that is barred under federal antitrust law.

Accordingly, while we believe that it would be possible to structure a joint liability trial with all plaintiffs, the Individual Plaintiffs object to a joint damages trial with the End Payor Plaintiffs. We look forward to discussing this issue with you on January 29, 2015.

Very truly yours,

/s/ *Moira Cain-Mannix*

Moira Cain-Mannix

MCM/rab

cc: all parties (via electronic mail)

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January 22, 2015

VIA ELECTRONIC MAIL

The Honorable Mitchell S. Goldberg
United States District Judge
7614 U.S. Courthouse
601 Market Street
Philadelphia, PA 19106-1766

Re: ***Vista Healthplan, et al. v. Cephalon, Inc., et al.***
Case No. 06-1833 (E.D. Pa.)

Dear Judge Goldberg:

End-Payor Plaintiffs submit this letter in advance of the January 29, 2015 Status Conference to address issues relevant to the anticipated trial of this matter. As they have done in the past, End-Payor Plaintiffs will continue to work with the other Plaintiff groups to coordinate and streamline our presentations. We believe that a trial should be set at the earliest possible date and that a joint liability and causation trial could be conducted over the summer.[1]

End-Payor Plaintiffs suggest that the Court conduct a bifurcated trial beginning with a consolidated, single jury trial on the common aspects of liability and causation.[2] The joint liability and causation phase will include findings on Plaintiffs' *Walker Process* and *Actavis* claims based on the common evidence.

Following the initial joint liability and causation phase, the End-Payor Plaintiffs and Direct Purchaser Plaintiffs will try antitrust impact and damages to separate juries to avoid potential jury confusion.[3] End-Payor Plaintiffs suggest that they be allowed to conduct their

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[1] It is the End-Payor Plaintiffs' understanding that all issues concerning the FTC's claims will be tried as a bench trial, but that issues of liability and causation substantially overlap across all Plaintiff groups.

[2] *See In re Playmobile Antitrust Litig.*, 35 F. Supp. 2d 231, 248 (E.D.N.Y. 1998); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 326 (E.D.Mich. 2001); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 523 (S.D.N.Y. 1996).

[3] Recently in the *Nexium* antitrust litigation, the court bifurcated the trial between liability and damages with the End-Payor Plaintiffs' damages claims to be tried to a jury separate from the Direct Purchaser Plaintiffs. *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-2409, transcript at 11 (D. Mass. Dec. 11, 2013). *See also, In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-2409, 2013 U.S. Dist. LEXIS 162276, at *42, 50 (D. Mass. Nov. 14, 2013) ("[T]he possibility of multiple proceedings after a class-wide liability determination hardly offends the rights of any of any of these litigants.").

antitrust impact and overcharge damages claims first, utilizing the jury that was empanelled to render a verdict in the initial joint trial phase.[4]

Having separately empanelled juries decide the antitrust impact and damages claims of End-Payor Plaintiffs and Direct Purchaser Plaintiffs makes the most sense in that it avoids issues of prejudice – including those that arise when there are multiple sets of plaintiffs occupying different positions and issues of pass-through are present – and would not violate the Seventh Amendment as an appropriately drafted verdict form in the initial joint liability and causation phase would ensure that the subsequent juries did not reexamine any issues decided by the first jury. *See Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995) (holding Seventh Amendment requires only that the court "not divide issues between separate trials in such a way that the same issue is reexamined by different juries").

Following the verdict entered in the initial liability and causation phase, the Court will determine the states for which the End-Payor Plaintiffs have established liability (with the exception of the "antitrust impact" liability element, which is reserved for the impact and damages phase).

Regarding the remaining schedule, one factor the Court should consider is that the End-Payor Plaintiffs have a pending motion for class certification. Based on the size of the class and our past experience, we believe the notice process can be completed in 90 to 120 days from the date the class is certified. Given indications provided by the Court on the timing of all pre-trial matters, End-Payor Plaintiffs believe a late summer trial date is feasible.

Finally, End-Payor Plaintiffs bring to the Court's attention yesterday's ruling by the First Circuit, which upheld certification to a class of end-payor insurers and consumers in the *Nexium* pay-for-delay case.[5] The Defendants here oppose class certification with many of the arguments rejected by the trial court and now the First Circuit, including analysis from the same defense expert, James Hughes. End-Payor Plaintiffs are submitting a separate Notice of Supplemental Authority on the *Nexium* ruling.

We will, of course, be prepared to discuss all of these issues in greater detail at the status conference.

Sincerely,

John A. Macoretta

cc: All Counsel (via electronic mail)

[4] As contemplated by controlling law, federal antitrust law does not preempt recovery under state law, and recovery under state law is cumulative to recovery under federal law. *See California v. ARC Am. Corp.*, 490 U.S. 93, 101-102, 105 (1989).

[5] *In re Nexium Antitrust Litigation*, Case No. 14-1521, (1st Cir. Jan. 21, 2015).

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, DC 20580

Bureau of Competition
Health Care Division

January 22, 2015

The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
601 Market Street
Room 4000
Philadelphia, Pennsylvania 19106-1797

Re: *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (MSG) (E.D. Pa.), and Related Cases

Dear Judge Goldberg:

The Federal Trade Commission respectfully submits this letter in advance of the January 29, 2015 status conference. The FTC is committed to resolving its law enforcement action against Cephalon as efficiently as possible. We support the Court's proposal to schedule a trial for this summer, and we continue to believe that the best course is to proceed first with a bench trial of the FTC's claims against Cephalon. This letter outlines our position on these issues.

The FTC Supports Setting a Trial Date and Corresponding Pretrial Schedule

We strongly support the Court's proposal to set a firm trial date for this summer. A summer trial date provides ample time for the parties and the Court to prepare for trial, a process that can and should begin as soon as the pending summary judgment motions are decided.[1]

To ensure these preparations proceed on schedule, we recommend that the Court set or approve a pretrial schedule as soon as practicable. As part of that schedule, the FTC recommends setting a relatively early date for the filing of pretrial memoranda under Local Civil Rule 16.1(c). We envision that these memoranda would identify the fact and expert witnesses that each party may call, indicate the cases in which each witness may testify (as an example, the Court has already

[1] In its August 28, 2014 letter to the Court, Cephalon asked that the Court not consider a trial schedule until the Court has disposed of all *Daubert* and class certification motions, as well as a "forthcoming" motion to strike the FTC's disgorgement remedy. Letter from J. Burling to Judge Goldberg, Aug. 28, 2014 ("Cephalon Aug. 28 Letter"), at 1, 4. The FTC strongly disagrees that such delay is necessary. These motions can be considered as part of the normal pretrial schedule. And with regard to Cephalon's "forthcoming" motion to strike, though Cephalon stated that it would file this motion shortly, it has not done so for the past five months. The FTC therefore doubts that such a motion would be timely. Federal Rule of Civil Procedure 12(f)(2) states that a motion to strike must be made "within 21 days after being served with the pleading." Regardless, questions about the appropriateness of the FTC's requested relief are most properly addressed after trial.

precluded Cephalon's ten patent experts from testifying in the FTC's case), and briefly outline the subject matter for each witness's testimony. These submissions would provide the parties and the Court with more concrete information about the likely content and scope of each potential trial. The Court could also use this information to make a final decision on the trial structure.

A Joint Trial Would Be Cumbersome, Inefficient, and Contrary to Public Policy

In its July 2014 patent evidence opinion, this Court held that the FTC is entitled to collateral estoppel on the issues of patent invalidity and inequitable conduct, and that Cephalon is foreclosed from "any attempt to use the strength of its patent, or litigation uncertainty and business risk, as a defense to the FTC's claim."[2] The other plaintiffs, who will be trying their claims to a jury, are entitled to collateral estoppel on invalidity but not inequitable conduct.[3] As a result of these different evidentiary rulings, a joint trial would be logistically difficult and would offer only limited efficiency benefits. Consolidation would also prejudice the FTC.

A joint trial would be administratively difficult and would substantially inconvenience the jurors. Cephalon, in its August 28 letter to the Court, argues that a joint trial would be straightforward because "the jury is permitted to hear evidence regarding the patent, and to the extent such evidence is irrelevant to the FTC's case, the Court can disregard that evidence in ruling on that claim."[4] But Cephalon overlooks that the FTC will seek to confront Cephalon's fact and expert witnesses with the established fact that Cephalon procured its patent through inequitable conduct. The Court would either need to shuttle the jury in and out of the courtroom to avoid these exchanges, or have the FTC conduct its examination outside the presence of the jury—resulting in substantial down time for the jurors. Moreover, because the FTC would not be able to control when hostile witnesses raised Cephalon's patent (or litigation uncertainty) as a defense, it would be difficult to predict when the jury would need to be excused.

The FTC's non-shared experts create a similar problem. Several of the FTC's experts are not a part of the private plaintiffs' cases, including its two primary experts in economics and negotiation: Professors Roger Noll and Max Bazerman, respectively. These experts would need to testify outside the presence of the jury, and making time for this during the jury trial would result in the jury being empaneled for significantly longer than it would otherwise need to be.

In addition to these administrative difficulties, a joint trial would prejudice the FTC by impairing its ability to present its claim. A large portion of the evidence at a joint trial would relate to Cephalon's patent. Patent evidence will be highly relevant to the private plaintiffs' *Walker Process* claims and Cephalon has indicated that it intends to offer patent evidence for the reverse-payment claims as well. Indeed, Cephalon has indicated it intends to introduce up to ten patent experts.[5] This additional patent evidence would, by necessity, repeatedly interrupt the

[2] Mem. Op. at 15, July 29, 2014 (doc. 322).

[3] Mem. Op., Mar. 13, 2014 (doc. 266).

[4] Cephalon Aug. 28 Letter at 2.

[5] Cephalon Aug. 28 Letter at 4 (acknowledging that its ten patent experts are precluded from the FTC case but asserting that they are still relevant to the private plaintiffs' case).

FTC's case. Additionally, the FTC's primary experts would have to testify whenever the Court could fit them in, possibly in a piecemeal manner before or after the jury proceedings. A joint trial would also result in considerable additional expense to the government, which would have to pay to maintain a trial team in Philadelphia for the entirety of the joint trial rather than a shorter FTC-only trial. Finally, as the FTC previously has explained, public policy favors allowing the government to proceed with its own trial.[6] The FTC is not aware of any antitrust case in which the court has ordered the government to participate in a joint antitrust trial over its objection.

The administrative difficulties and prejudice to the FTC that would result from a joint trial substantially outweigh any efficiencies. *See Farahmand v. Rumsfeld*, No. 02-cv-1236, 2002 WL 31630709, at *1-2 (E.D. Pa., Nov. 20, 2002) ("In exercising its discretion to consolidate, a court should weigh the benefits of judicial economy against the potential for delay, confusion, or prejudice."). This is especially so because a joint trial will not create many efficiencies. For the reasons described above—separate claims, separate experts, and different testimony with regard to Cephalon's patent—the overlap between the FTC's case and the private plaintiffs' case is ultimately likely to be limited. *See In re Ampicillin Antitrust Litig.*, 88 F.R.D. 174, 177-78 (D.D.C. 1980) (denying motion to consolidate where "a consolidated trial would likely consume more time and expense than separate trials").

For these reasons, the limited benefits of consolidation are significantly outweighed by the prejudice to the FTC and especially by the likelihood of substantial inconvenience to the jury. *See United States v. Corning Glass Works*, No. 3:90-cv-207, 1991 WL 329759, at *1 (M.D. Pa. Sept. 16, 1991) ("A bifurcated trial will thus be more convenient for a jury and the inconvenience to the witnesses is a small price to pay for the convenience of the jurors.").

The FTC's Case Should Proceed to Trial Even if the Private Actions Are Delayed

Regardless of how the Court ultimately decides to structure the trials in these cases, the FTC believes that its case against Cephalon should proceed expeditiously to trial. If issues such as class certification delay the private cases longer than anticipated, the FTC strongly recommends that the Court proceed with a trial of the FTC's case this summer.

Sincerely,

Markus H. Meier
Attorney for Plaintiff Federal Trade Commission

[6] *See* FTC Letter to Judge Goldberg, Aug. 28, 2014.

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January 22, 2015

VIA E-MAIL

The Honorable Mitchell S. Goldberg
7614 James A. Byrne U.S. Courthouse
United States District Court for the
Eastern District of Pennsylvania
601 Market Street
Philadelphia, Pennsylvania 19106-1797

RE: Apotex, Inc. v. Cephalon, Inc., et al., No. 2:06-cv-2768-MSG

Honorable Judge Goldberg:

We write on behalf of Apotex in response to your January 6, 2015 order allowing for correspondence regarding trial scheduling and structure.

Apotex proposes setting a certain trial date, and it is amenable to a summer trial. Apotex requests a single trial on liability and damages for its claims.

As set forth in previous briefing, Apotex's position is that several elements of Apotex's antitrust claims -- including, without limitation, Cephalon's intent to deceive the U.S.P.T.O. in securing the '516 patent -- have already been established because of, *inter alia*, application of the mandate rule and law of the case. While Apotex recognizes the Court has already ruled on this issue, Apotex respectfully reserves its rights, and therefore objects to any fact-finder reconsidering anew the issue of Cephalon's intent or any other fact or element addressed in the Court's patent decisions. Accordingly, specific to the issue of consolidated trials, Apotex objects to the extent consolidation would cause a fact-finder to reconsider these issues, or facts relating thereto, in relation to Apotex's antitrust claims.

Sincerely,

Brian Sodikoff

Brian J. Sodikoff

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January 22, 2015

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By E-mail

The Honorable Mitchell S. Goldberg
United States District Court Judge
United States District Court
for the Eastern District of Pennsylvania
601 Market Street
Philadelphia, PA 19106

Re: *In re Modafinil*, Civ. A. Nos. 06-1797, 06-1833, 06-2768, 08-2141

Dear Judge Goldberg:

Pursuant to the Court's January 6, 2015 order, I write on behalf of Defendant Cephalon, Inc. ("Cephalon") to address issues concerning trial scheduling and structure in advance of the January 29, 2015 status conference.

In regard to trial scheduling, a number of issues need to be resolved prior to trial, and any trial date of course will need to take into account the time required for resolution of these issues. As the Court recognized in its January 5, 2015 email to the parties, the pending class certification and *Daubert* motions are among the most significant open issues, but there are several others, as identified below. As to trial structure, Cephalon continues to believe that it should not have to defend the same claims, based on the same evidence, in multiple, repetitive trials, as set forth in Cephalon's August 28, 2014 letter to the Court. It may be appropriate to phase or even bifurcate certain issues for trial (e.g., damages, *Walker Process*, individual settlements), but ultimately that more detailed structuring may depend on how the Court resolves these key open issues.

Class Certification. Class certification procedures, including notification of class members, necessarily impact trial scheduling. Whether the proposed classes of direct and indirect purchasers in this case satisfy the requirements of Rule 23 turns on a number of factual disputes Defendants highlighted in their June 19, 2014 opposition briefs. The Third Circuit mandates a "rigorous analysis" of these issues, requiring courts "to consider carefully all relevant evidence and make a definitive determination that the requirements of Rule 23 have been met ...." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316, 320 (3d Cir. 2008). Given this exacting standard, Cephalon believes the Court should hold an evidentiary hearing on the disputed factual issues raised in these motions. And if the Court ultimately determines that either or both of the proposed classes meets the requirements for certification under Rule 23, some time will be required to send notice to class members, and to provide those members an opportunity to opt out of the class. *See* Fed. R. Civ. P. 23(c)(2).

Daubert Motions. As the Court recognized in its January 5, 2015 email, a number of *Daubert* motions are pending. These motions obviously bear heavily on trial preparation, and Cephalon appreciates that the Court intends to decide those motions well in advance of trial.

FTC Disgorgement Motion. Unless obviated by the Court's upcoming decision on the pending summary judgment motions, Cephalon will be filing a motion to preclude the FTC's tardily asserted disgorgement claim. As the Court may recall, once the FTC's primary prayer for relief in this case (compelling generic entry of modafinil) became moot in 2012, the Commission asserted for the first time a demand for billions in disgorgement—a remedy the Commission had expressly, repeatedly, and strategically disavowed for years in this case. *See, e.g.*, Hearing Tr., Civ. A. No. 06-1797, Dkt. 71, at 61:8-14 (April 22, 2010) ("We're not seeking damages. We don't have the authority to do that. We're not seeking any kind of monetary relief. We're seeking only an injunction…."). Monetary remedies not only have been expressly waived by the Commission, but they also exceed the Commission's statutory authority and in any event cannot be supported by traditional principles of equity given the undisputed facts in this case. Cephalon previously addressed that disgorgement claim in the context of a broader motion to dismiss for lack of jurisdiction. While the Court denied that motion, holding that the FTC's overall equitable case against Cephalon was not moot, it expressly reserved judgment on whether the Commission was entitled to pursue a disgorgement remedy. *See* Mem. Op., Civ. A. No. 08-2141, Dkt. 322, at 2, n.2 (July 29, 2013). Resolution of this issue will have an important impact on the scope and complexity of trial.

Patent Rulings. While the Court has decided that its previous findings of invalidity and materiality preclude Cephalon from re-litigating those issues in the forthcoming antitrust trial, it has not addressed whether or how those findings may be presented to the jury in the context of the *Actavis* claims (which should be evaluated as of the time of the agreement and not based on subsequent patent findings)[1] or the intent prong of *Walker Process* (which should be decided independent of materiality, *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1358-59 (Fed. Cir. 2011)). At some point prior to commencement of trial, Cephalon respectfully submits that the Court should address how to avoid unfair prejudice that would result from inappropriately injecting these subsequent patent rulings into the antitrust trial.

Standard Pre-Trial Proceedings. Even after these preliminary issues are decided, significant pre-trial work will remain. Given the complexity of the claims asserted, standard pre-trial filings and submissions—including motions *in limine*, witness lists, deposition designations, exhibit

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[1] *See* Mem. Op., Civ. A. No. 08-2141, Dkt. No. 322 at 8-9 (July 29, 2014) ("An invalidity claim litigated to verdict can have only two outcomes: the patent is valid or it is not. Prior to verdict, the parties are likely to disagree in good faith about the merits of the claim: 'No one can be certain that he will prevail in a patent suit.' The fact that a patent's strength is a spectrum does not change simply because a judge later determines that the patent was, in fact, invalid all along. Cf. 35 U.S.C. § 282(a) ('A patent shall be presumed valid.').") (citations omitted).

lists, pretrial statements, and stipulations—will be a substantial undertaking for the parties and the Court.

The foregoing issues present a number of variables that make it challenging to set a firm trial date and definitively determine trial structure at this time. Certainly, a schedule could be set to address each of the issues listed above, as well as a target date for trial (though given the time required to address the issues listed above, a summer trial date seems difficult). In addition, Cephalon respectfully suggests that the Court defer the specifics of structuring the trial until after resolving the key issues above, perhaps setting a schedule for the parties to submit specific structuring proposals after they have had an opportunity to consider the implications of these rulings.

Sincerely,

/s/ James C. Burling

James C. Burling

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Re: *In re Modafinil*, 06-1797, 06-1833, 06-2768

Dear Judge Goldberg:

I write on behalf of Defendants Teva Pharmaceuticals Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), and Barr Laboratories, Inc. ("Barr") in response to the Court's Order of January 6, 2015 inviting the parties to outline their positions regarding trial scheduling and structure and other issues that should be addressed at the status conference set for January 29, 2015. Although we have some tentative views on these subjects, we do not expect to finalize them until we have had the opportunity to review the court's upcoming summary judgment ruling. In the meantime, here are some of the issues that we believe warrant discussion at next week's hearing:

1. Class Certification

One of the most important issues affecting trial preparation and the timing and scope of any trial is class certification. Plaintiffs seek certification of a direct purchaser class and an end-payor class. Although plaintiffs' certification motions are fully briefed and ready for argument, Teva and Barr believe that the Court should hold an evidentiary hearing so that it can conduct the "rigorous analysis" required under Rule 23. *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316-20 (3d Cir. 2008). With respect to the direct purchasers' motion, there is an important factual dispute regarding the number of class members and whether joinder is impracticable given that the proposed class is not only small, but dominated by three large companies. No court has ever certified such a class. (*See, e.g.*, Defs.' Opp'n to DPP Class Cert. Mot. (June 19, 2014).) There are also important factual disputes that warrant an evidentiary hearing with respect to the end-payors' motion, including, in particular, whether the members of

such a class are ascertainable. (*See, e.g.*, Defs.' Opp'n to EPP Class Cert. Mot. (June 19, 2014).)[1]

The class certification proceedings will have important trial scheduling implications. Not only must the motions themselves be decided, but even assuming the Court were to certify a class, it then must afford class members notice and a sufficient opportunity for them to opt-out.

For these reasons, Teva and Barr propose that the Court set the class certification motions for hearing and defer setting a trial date until after class certification proceedings are completed.

2. Daubert Motions

Numerous motions relating to the admissibility of expert testimony are pending. Because these motions have important implications for trial preparation, it would be useful to discuss when and how they will be decided and whether the Court will conduct evidentiary hearings relating to them.

3. The FTC Role at Trial and Its Disgorgement Claim

The status conference should include a discussion of the anticipated role of the FTC at a jury trial involving the claims of the private plaintiffs. The only claim the FTC has brought is an *Actavis* claim against Cephalon, which the Court will decide. To avoid confusing the jury, we believe that the FTC should be a "silent participant." The Court, for efficiency purposes, should permit the FTC (and Cephalon) to designate and adopt portions of the trial record relating to the claims of the private plaintiffs and then, following the conclusion of the jury trial, the Court can conduct supplemental proceedings relating to the FTC's claim against Cephalon.

Another important issue relating to the FTC concerns its late-filed claim for "disgorgement." Although that claim most directly affects Cephalon, it also affects other defendants insofar as the FTC apparently seeks to recover in the guise of disgorgement some of the same damages the private plaintiffs seek to recover from the Generic Defendants. We understand that Cephalon plans to file a motion to dismiss the FTC's disgorgement claim. Because of that claim's damages implications, we ask that the Court resolve that motion in advance of any trial.

4. The Court's Patent Rulings

[1] Fed. R. Civ. P. 23(f) affords parties the right to appeal certification decisions.

The status conference should include a discussion of precisely what the Court intends to tell a jury about its findings concerning the validity of Cephalon's RE '516 patent. Although the Court's collateral estoppel ruling acknowledged the generic defendants' concern about the risk of unfair prejudice and confusion, ruling did not resolve what, if anything, the Court would actually say about its patent rulings:

> My decision not to instruct the jury that Cephalon obtained its patent by fraud should eliminate most of the Generic Defendants' concerns that they will be prejudiced at trial. At most, the jury will only be instructed that Cephalon's patent—which the Generic Defendants were accused of infringing—was later found to be invalid, and that certain omissions were "material." This is quite different than advising the jury that Cephalon committed fraud on the PTO.

Mar. 13, 2014 Op. (Dkt. No 600) at 24-25.

Teva and Barr believe that it would be inappropriate for the Court to tell the jury anything about its prior ruling and its conclusions concerning the validity of Cephalon's patent. Doing so would unfairly prejudice the generic defendants, who entered their settlements without the benefit of the ruling that this Court made nearly five years later and did not participate in the trial that led to that ruling. This is an important issue and could materially affect defendants' views about potential trial structures.

5. Separate or Staged Proceedings

The status hearing should include a discussion of the merits of separate or staged proceedings. A single trial that includes all parties and encompasses all claims is likely to be unwieldy and raise formidable, ongoing case management challenges. Separate or staged proceedings are a potential solution. For example:

> Damages: Teva and Barr submit it may be appropriate to bifurcate liability and damages and that there should be separate damages trials for the direct and indirect purchasers, as plaintiffs themselves have suggested. Bifurcation could avoid conflicts between direct and indirect purchasers, save time in the event plaintiffs do not prevail on their liability claims, and allow for shorter, more manageable, and more focused trials.
>
> The *Actavis* Claims: With conspiracy out of the case, there is less justification for trying the claims about each of the four settlements in a single proceeding. That approach would increase the risk of jury confusion and make it more likely that the jury will not decide each settlement on its independent merits. Plaintiffs

already have made clear that they will try to exploit this risk. Some of their experts, for example, have offered opinions that aggregate the values they assign to the different settlements. Although firm instructions and evidentiary limitations are one way to address the risk of confusion, separate trials or phased proceedings are another.

The *Walker Process* Claim: Plaintiffs' *Walker Process* claim is asserted only against Cephalon, and the evidence relating to that claim is materially different from the evidence relating to the *Actavis* claims against the generic defendants. One issue for discussion is whether the *Walker Process* claim should be separated in some manner, perhaps through some type of phased trial. Defendants will be prepared to discuss this issue in more detail at the hearing.

The FTC Claim: As noted above, Teva and Barr believe that the FTC's claim, which the Court will decide, is best addressed through supplemental proceedings following the conclusion of any jury trial. This approach would promote efficiency and avoid duplication by giving the FTC (and the Court) the benefit of the record that results from proceedings before the jury.

6. Trial Date/Schedule

Once the Court resolves the class certification issue and pending Daubert motions, there still will be much work to be done before this case is ready for trial, including completing the pretrial tasks addressed by the local and Federal Rules relating to such things exhibit lists, witness lists, deposition designations, pretrial statements, and stipulations. *See, e.g.*, Local Rule 16.1(c) & (d).

In light of the open issues, and also taking into account some potential scheduling conflicts of defense counsel and certain witnesses, Teva and Barr believe that a summer trial is likely too ambitious. We believe a late 2015 trial target is much more realistic. We note that the Court's rulings on summary judgment, class certification, and *Daubert* motions may affect the parties' positions (and the Court's own views) concerning trial structure and timing.

We look forward to discussing these issues at the January 29 status hearing.

STEVENS & LEE

Sincerely,

/s/ Joseph E. Wolfson

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January 22, 2015

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The Honorable Mitchell S. Goldberg
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601 Market Street
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Re: *In re Modafinil*, 06-1797, 06-1833, 06-2768

Dear Judge Goldberg:

This letter is submitted on behalf of Generic defendants Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. and Mylan Inc. and Mylan Pharmaceuticals Inc. (the "Ranbaxy and Mylan Defendants") in response to the Court's January 6, 2015 Order inviting the parties to file short statements in advance of the January 29, 2015 status conference. Given that the Court's pending opinion on the summary judgment motions will shed light on the issues that remain for trial, if any, and will likely substantially affect the course of the litigation as a result, this statement is preliminary at this juncture.

Pre-trial matters

Class Certification

If the Court were to deny the Ranbaxy and/or Mylan Defendants' motions for summary judgment, the Court would then need to consider the pending motions by the direct and indirect purchasers for class certification. In light of the substantial disputed factual and expert opinion issues presented in those motions, Defendants have requested an evidentiary hearing on class certification.

***Daubert* Motions**

The parties filed numerous *Daubert* motions, which were dismissed without prejudice by the Court for administrative reasons. These motions need to be refiled/reinstated, and decisions on the issues raised in these motions should precede any trial. A hearing may be warranted on one or more of the *Daubert* motions.

Trial

The Court's January 5, 2015 e-mail indicated that it is "leaning toward one trial, all parties." The Ranbaxy and Mylan Defendants have significant concerns about such a trial, and believe that their rights would be substantially prejudiced if the Court proceeded with trial in this way. There are claims asserted against Cephalon, such as the *Walker Process* claim made by some Plaintiffs, that are separate and distinct from the *Actavis* claims against the Ranbaxy and Mylan Defendants. These claims involve evidence that relates solely to Cephalon's liability on those distinct issues, and should not be admissible against the generic companies, such as the Ranbaxy and Mylan Defendants. *See* November 7, 2011 Amended Memorandum Opinion. In addition, the Court has made separate findings in the Apotex/Cephalon patent case, to which the Generic Defendants were not parties and which "the Generic Defendants are not bound by." *See* March 13, 2014 Memorandum Opinion at 3.

The prejudice and jury confusion that will result from the presentation of all of the evidence and prior rulings against Cephalon in one trial involving all of the parties cannot simply be cured by an instruction from the Court. *See Klimaski v. Parexel Int'l*, No. CIV. A. 05-298, 2005 WL 857350, at *5 (E.D. Pa. Apr. 4, 2005) (separate trials ordered because evidence admissible for the purposes of one party's claim not admissible or relevant to the claims of the other parties and the differences "would be extremely difficult for the jury" to understand, "even if given limiting instructions").

The Ranbaxy and Mylan Defendants face particular prejudice and jury confusion from the Walker Process claim and related evidence about Cephalon. Jury confusion and bias can manifest as "prejudice-from-a-negative-label," where factually unrelated claims can skew a jury's overall impression of a party. *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, No. CIV.A 09-80-JJF-MPT, 2010 WL 925864, at *2 n.8 (D. Del. Mar. 11, 2010) (citing *Hunter Douglas, Inc. v. Comfortex Corp.*, 44 F. Supp. 2d 145, 154 (N.D.N.Y. 1999) (analyzing "prejudice-from-a-'negative label' theory" as a factor in deciding whether to sever infringement and antitrust claims)). This presents the risk of liability by association. *Philips Elecs. N. Am. Corp. v. Contec Corp.*, 220 F.R.D. 415, 418 (D. Del. 2004) (stating that there would be "a substantial risk of prejudice" if the jury believed the defendants were linked). In *Philips Electronics*, the plaintiff in a patent infringement suit joined another defendant, but did not allege that the claims of infringement were related or that the defendants were joint and severally liable. *Philips Elecs. N. Am. Corp.*, 220 F.R.D. at 416–17. The district court determined that "justice will thus be served" by severing the defendants and conducting separate trials. *Id.* at 418.

Finally, a single trial could well result in the jury not focusing on the individual merits of each Generic Defendant's facts and positions, or the unique facts and circumstances involved in each Generic company's separate and independent settlement with Cephalon. *See Klimaski*, 2005

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WL 857350, at *5 ("Proceeding in a single action will "deflect the jury's attention from the merits of each individual plaintiff's claim."); *see also Lover v. District of Columbia*, 248 F.R.D. 319, 325 (D.D.C. 2008) (prohibiting the joinder of differing claims when "problems in the presentation of evidence would prejudice the defendants and prevent the jury from focusing on each plaintiff's individual claim."). In fact, this has been the Plaintiffs' central strategy employed at every opportunity and should not be promoted through the use of one trial for all Defendants. *See, e.g.*, End-Payor Pls. Opp'n Defs. Summ. J. 1, 8, 24 n.54, 32 (asserting liability for all Defendants based on the alleged $300 million in total payments to the Generic Defendants); Apotex's Comb. Mem. Opp'n Defs. Summ. J. 3, 17, 21 (same).

For these reasons, the Ranbaxy and Mylan Defendants believe that claims against the Generic Defendants should be tried separately from the claims against Cephalon.[1] *See Sporia v. Pa Greyhound Lines*, 143 F.2d 105, 107 (3d Cir. 1944) (parties can be severed at the court's discretion, to separate trials when demanded by "[e]ssential justice, and the proper determination of the rights and liabilities.").

The Ranbaxy and Mylan Defendants anticipate that following decision on class certification, there will be the need for fairly extensive pretrial proceedings to determine how the trial(s) will be conducted and when a trial (or trials) could reasonably proceed.

Sincerely,

J. Douglas Baldridge, Esq.

Counsel for Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc.

On behalf of the Ranbaxy and Mylan Defendants

[1] The Ranbaxy and Mylan Defendants strongly object to the suggestion previously made by the opt-out direct purchaser plaintiffs that their claims could be tried prior to hearing on class certification and in conjunction with trial of the FTC's claims against Cephalon.